

Guidelines for Health Care Providers: The Consent Process for SARS-CoV RT-PCR and EIA Testing at CDC and Public Health Laboratories

CDC has distributed a SARS-CoV RT-PCR assay under an FDA investigational device exemption (IDE) and an EIA assay to state and local public health laboratories to test specimens for SARS-CoV. These tests are used to evaluate persons suspected of having SARS-CoV disease. The RT-PCR assay is used to test for SARS-CoV viral RNA in respiratory samples, stool, plasma, or serum. The EIA test is used to detect SARS-CoV antibodies in blood or serum specimens. A signed consent form for performance of each test is recommended because neither test has been licensed by the FDA and the RT-PCR test is being used under an FDA-approved IDE. A signed consent form is also required for storage of specimen remainders for future investigations.

To submit specimens for SARS-CoV RT-PCR or EIA testing, healthcare providers should follow these steps:

1. **Consult Public Health (206-296-4774)** to determine if SARS-CoV testing is indicated.
2. **Seek informed consent** from the patient for testing.
The RT-PCR consent form can be found at:
<http://www.cdc.gov/ncidod/sars/lab/rtpcr/consent.htm>.
The EIA consent form can be found at:
<http://www.cdc.gov/ncidod/sars/lab/eia/consent.htm>
3. **Collect specimens** for testing. Guidelines for specimen collection can be found at
<http://www.metrokc.gov/health/sars>.
4. **Submit specimens**, with a completed specimen submission form, to the state or local public health laboratory. Include the consent form, retaining the signed consent form copy for your records. Specimens will be tested at the reference public health laboratory. Final results will be reported to you through Public Health. Information on interpreting these test results is provided at
<http://www.metrokc.gov/health/sars>.
5. **Deliver test results** to the patient. Provide a patient information sheet/consent for long-term specimen storage to the patient along with the test results. Specimen remainders stored long term may be used for future investigations.
The RT-PCR patient information sheet/consent for long-term specimen storage can be found at:
<http://www.cdc.gov/ncidod/sars/lab/rtpcr/participant.htm>.
The EIA patient information sheet/consent for long-term specimen storage can be found at:
<http://www.cdc.gov/ncidod/sars/lab/eia/participant.htm>.
6. **If a signed patient information sheet/consent for long-term storage is obtained, fax it to CDC.**

Consent Form:

SARS Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) Testing

The Centers for Disease Control and Prevention (CDC) and public health laboratories are using an experimental laboratory test as one tool in a public health response to the "severe acute respiratory syndrome" (SARS) outbreak. The Food and Drug Administration (FDA) has not approved this test. We don't know for sure if this test can detect all people who may get sick with SARS. There are no proven tests that quickly find the virus.

Your State Health Department and/or CDC are using this test as one tool to help us find out if people are infected. We are using this test to respond to the SARS outbreak and limit spread of this illness.

Background

SARS is a respiratory illness that can start as fever and cough. It may go on to pneumonia in some people. SARS seems to be spread by close person-to-person contact. SARS may also spread by touching the skin of other people or objects with infected droplets and then touching your eye(s), nose, or mouth. This can occur when someone who is sick with SARS coughs or sneezes droplets onto themselves, other people, or nearby surfaces. It also is possible that SARS can be spread through the air or by other ways that we don't yet know about.

Why Should My (My Child's) Sample Be Tested?

We are asking you (your child) to be tested for the SARS-related virus because you (your child):

- Have symptoms that resemble those of SARS, and/or
- Had traveled 10 days before start of symptoms to an area that had reported SARS cases, and/or
- Have cared for, lived with, or had direct contact with a patient with suspected SARS.

Are There Any Benefits?

There may be no direct benefits to you (your child) from having this test done. This test may help to find the virus in people who do not yet have all the signs of SARS. If people with the SARS virus limit contact with other people, this can prevent others from getting sick. By having this test done, you could lower the chance of spreading the virus from you (your child) to your family or others. Use of this test could also help us to know more about this virus to help stop the spread of this illness. Some or all of these may benefit you (your child).

Are There Any Risks?

There is a small chance that this test may give a positive result for the SARS virus when the virus is not present (*false-positive*). If your (your child's) result from this test is positive:

1. You (your child) could be asked to limit contact outside the home by not going to work, school, out-of-home childcare, church, or other public areas. You may also be asked to use a mask at home to limit the risk of spread of the virus. If you (your child) have had symptoms of SARS, you might be asked to follow these limits because of these symptoms and not because of the test results. However, if your (your child's) samples tested positive, there is a small chance that you (your child) may be asked to follow these limits even if you (your child) have no symptoms.
2. There is no proven treatment for SARS at this time. If you (your child) your child is very ill, in rare cases, you (your child) may be advised to take an antiviral drug. You can refuse such treatments, but if you take them, they might cause side effects.
3. Based on the testing results, your (your child's) doctor may choose to change how your care will be managed.

This test may give a negative result when you (your child) actually have the virus (*false-negative*). A false-negative result should not have an effect on your (your child's) care. CDC has told doctors that a negative test does not prove that a person does or does not have the SARS virus. No changes in your medical care or how you interact with people around you should be based on a negative result.

Your (your child's) doctor will use other information along with this test to decide what is best for you (your child).

To do this test, extra samples may be collected that are like samples that are normally taken for laboratory testing when you are sick. These samples may include nasal swab or aspirate, or throat swab. The swabs are taken by placing one small Dacron swab into the back of your (your child's) nose and one into the back of your (your child's) throat for 5 seconds each. A nasal aspirate may also be done by placing and then, after a few seconds, removing 1-2 cc (less than ½ teaspoon) of salt water into each side of your (your child's) nose. These tests don't hurt, but may cause a little discomfort. Occasionally they make people gag, cough, or get a bloody nose.

Are There Other Choices?

There are no other rapid laboratory tests approved by FDA that can be used to tell whether you (your child) have the virus believed to be causing SARS.

What About Privacy?

We will keep all facts about you (your child) as private as the law allows. CDC, FDA, the Local/State Health Department staff, and the person(s) who ordered your test (such as your Doctor) may see your/your child's results. When we present or publish papers about these tests, neither you (your child) will be identified.

What Are the Costs?

The test will be done by CDC or your health department at no cost. You, your insurer, Medicare or Medicaid will need to pay for other costs related to the testing, such as doctor's visits.

What Happens If You (Your Child) Are Harmed?

If you (your child) are harmed as a result of taking the samples, CDC will not pay the costs for hospital and medical care. You, your insurer, Medicare or Medicaid will need to pay those costs. You (your child) do not give up any legal rights that otherwise would be available to you (your child).

Right to Refuse

This testing is voluntary. It is your choice to have this testing done on you (your child). If you refuse to have the testing done, then you (your child) will not lose the right to get other health care because of not having results from these tests. Your doctor will take care of you (your child) in the same way they would take care of you (your child) if this test were not available.

Whom to Call If You Have Questions

Please call your doctor if you have any questions about this testing. If you have questions about your (your child's) rights as a participant in this testing program, please call the CDC Associate Director for Science at 1-800-584-8814. Leave a message including your (your child's) name, phone number and that the protocol # is 3911. Someone will call you back as soon as possible.

Consent Statement

I agree that this investigational laboratory testing can be done on samples collected from me (my child). I have read the above and have had my questions answered by _____.

Print Patient's Name: _____

Patient/Parent Signature: _____ Date: _____

Witness to Signature: _____ Date: _____

Physician Witness to Signature: _____ Date: _____

Consent for Sample Storage

Thank you for agreeing for you (your child) to be in this program. We are asking for your consent to store any remainders of your (your child's) samples used for SARS virus testing at CDC for future SARS-related research. If the results of any future tests are important for your medical care we will make every effort to notify your physician.

We will not do human genetic testing or HIV testing unless we contact you and ask for your consent. If you agree to storage and change your mind later please fax Suzette Bartley at 404-639-0590.

☐ Yes, I agree to long-term storage of my (my child's) samples for future testing

☐ No, I do not agree to long-term storage of my (my child's) samples for future testing

Print Patient's Name: _____

Patient/Parent Signature: _____ Date: _____

NOTE: PLEASE RETURN OR FAX A SIGNED COPY OF THIS FORM TO

Suzette Bartley
Centers for Disease Control and Prevention
1600 Clifton Rd. Mailstop L02
Atlanta, Ga. 30333
FAX: 404-639-0590

Consent Form:

SARS Coronavirus Antibody Testing

Background

Severe Acute Respiratory Syndrome, or SARS, is a respiratory illness caused by a virus. It can start as fever and cough. It may go on to pneumonia in some people and can be serious. SARS may spread easily from person to person. The Centers for Disease Control and Prevention (CDC) and state and public health laboratories are using an experimental laboratory test to help detect people who have been infected with the SARS virus. This test is one tool in a public health response to the SARS outbreak to try to limit spread of this illness. The Food and Drug Administration (FDA) has not approved this test. We don't know for sure if this test can detect all people who may get sick with SARS. There are no proven tests that quickly find the virus.

Who Is Being Tested?

We are asking you (your child) to be tested for the SARS-related virus because you (your child):

- Have symptoms that are like the symptoms of SARS, and/or
- Had traveled 10 days before start of symptoms to an area that had reported SARS cases, and/or
- Have cared for, lived with, or had direct contact with a patient with suspected SARS.

Procedures

To do this test, we need a minimum of ¼ teaspoon of blood from children and 1 to 2 teaspoons of blood from adults. This blood may be taken using a needle put into a vein in your (your child's) arm. This test may also be done on blood that is left over after other tests for your (your child's) care are done.

We may also ask for a second blood sample more than 28 days after you (your child) became sick. We may ask for this second sample in order to test for SARS. This is because this test looks for evidence that the body is fighting the infection (antibodies), and sometimes it takes time for the body to make antibodies to fight the virus.

Are There Any Benefits?

There may be no direct benefits to you (your child) from having this test done. This test may help to show whether you (your child) have SARS. If people with the SARS virus limit contact with other people, this can prevent others from getting sick. By having this test done, you could lower the chance of spreading the virus from you (your child) to your family or others. It could also help us learn more about this virus to help stop the spread of illness.

Are There Any Risks?

When we take you (your child's) blood, the needle poke may pinch or sting or cause a bruise.

There is a small chance that this test may give a positive result for the SARS virus when the virus is not present (*false-positive*). If your (your child's) result from this test is positive:

1. You (your child) could be asked to limit contact outside the home by not going to work, school, out-of-home childcare, church, or other public areas. You may also be asked to use a mask at home to limit the risk of spread of the virus. If you (your child) have had symptoms of SARS, you might be asked to follow these limits because of these symptoms and not because of the test results. However, if your (your child's) samples tested positive, there is a small chance that you (your child) may be asked to follow these limits even if you (your child) has no symptoms.
2. Based on the testing results, your (your child's) doctor may choose to change how your care will be managed.

This test may give a negative result when you (your child) actually have the virus (*false-negative*). A false-negative result should not have an effect on your (your child's) care. CDC has told doctors that a negative test does not prove that a person does or does not have the SARS virus. No changes in your medical care or how you interact with people around you should be based on a negative result.

Your (your child's) doctor will use other information along with this test to decide what is best for you (your child).

Are There Other Choices?

You may refuse to be tested or to have your child tested. There are several other tests for the SARS virus, but they are all experimental and we don't know which tests work the best.

What About Privacy?

We will keep all facts about you (your child) as private as the law allows. CDC, FDA the Local/State Health Department staff, and the person(s) who ordered your test (such as your doctor) may see your/your child's results. When we present or publish papers about these tests, neither you (your child) will be identified.

What Are the Costs?

The test will be done by CDC or your health department at no cost. You, your insurer, Medicare or Medicaid will need to pay for other costs related to the testing, such as doctor's visits.

What Happens If You (Your Child) Are Harmed?

If you (your child) are harmed as a result of taking the samples, CDC will not pay the costs for hospital and medical care. You, your insurer, Medicare or Medicaid will need to pay those costs. You (your child) do not give up any legal rights that otherwise would be available to you (your child).

Right to Refuse

This testing is voluntary. It is your choice to have this testing done on you (your child). If you refuse to have the testing done, then you (your child) will not lose the right to get health care because of not having results from these tests. Your doctor will take care of you (your child) in the same way they would take care of you (your child) if this test were not available.

Whom to Call If You Have Questions

Please call your doctor if you have any questions about this testing. If you have questions about your (your child's) rights as a participant in this testing program or if you feel you have been harmed or injured by taking part in the program, please call the CDC Associate Director for Science at 1-800-584-8814. Leave a message including your (your child's) name, phone number and that the protocol # is 3918. Someone will call you back as soon as possible.

Consent Statement

I agree that this investigational laboratory testing can be done on samples collected from me (my child). I have read the above and have had my questions answered by _____.

Print Patient's Name: _____

Patient/Parent Signature: _____ Date: _____

Witness to Signature: _____ Date: _____

Physician Witness to Signature: _____ Date: _____

Consent for Sample Storage

Thank you for agreeing for you (your child) to be in this program. We are asking for your consent to store any remainders of your (your child's) samples used for SARS virus testing at CDC for future SARS-related research. If the results of any future tests are important for your medical care we will make every effort to notify your physician. We will not do human genetic testing or HIV testing unless we contact you and ask for your consent. If you agree to storage and change your mind later please fax Suzette Bartley at 404-639-0590.

☐ Yes, I agree to long-term storage of my (my child's) samples for future testing

☐ No, I do not agree to long-term storage of my (my child's) samples for future testing

Print Patient's Name: _____

Patient/Parent Signature: _____ Date: _____

NOTE: PLEASE RETURN OR FAX A SIGNED COPY OF THIS FORM TO

Suzette Bartley
Centers for Disease Control and Prevention
1600 Clifton Rd. Mailstop L02
Atlanta, Ga. 30333
FAX: 404-639-0590

Frequently Asked Questions About the Consent Process for SARS Testing

Where can I find information on how to report a possible SARS case and submit specimens for SARS-CoV testing?

Please call Public Health at 206-296-4774.

Why is a signed informed consent form recommended for SARS-CoV testing?

A signed consent form is recommended because neither the RT-PCR test nor the EIA test has been licensed by FDA and the RT-PCR test is being used under an FDA-approved investigational device exemption (IDE). In addition, consent is required to store specimen remainders for future investigations.

Why are there two different consent forms, one for RT-PCR and one for EIA?

Two forms are required because of differing IRB review requirements; CDC's IRB reviewed and approved two separate protocols.

What happens if I submit specimens for testing without a signed consent form?

Because of the potentially serious public health impact of SARS-CoV transmission, specimens that are received by a state or local public health laboratory without a signed consent form will still be tested.

What is the patient information sheet, and when do I use it?

The patient information sheet/consent for long-term specimen storage will be sent to the physician along with the patient's test results. The physician should provide this document to the patient. It explains to the patient why SARS-CoV testing was performed on their specimens, explains what the results mean, and asks the patient for permission to store specimen remainders for future investigations.

Why should a signed patient information sheet be returned?

The patient information sheet asks the patient for permission to store specimen remainders for future investigations. If a signed consent form is not received before testing, it is necessary to receive the signed patient information sheet to store any specimen remainders. Specimens without a signed informed consent or signed patient information sheet allowing long-term specimen storage must be destroyed.